BURN RELIEF CONTINUOUS- lidocaine spray
Safeway

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Signature Care Burn Relief Continuous Spray Lidocaine 0.5%

Lidocaine USP 0.50%

Purpose .....External analgesic

Uses Temporary Relief of pain and itching due to: sunburn, minor burns, minor cuts scrapes, insect bites, minor skin irritations

Warnings

For external use only

DO not use in large quantities, particularly over raw surfaces or blistered area

When using this product, avoid contact with eyes, use only as directed, do not puncture or incinerate, content under pressure, do not store at temperature above 120 F.

Stop use and ask a doctor if, condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children, In case of accidental ingestion seek professional assistance or contact a Poison Control Center immediately.

Direction, Shake well, adults and children 2 years of age and older: Apply to affected area no more than 3 to 4 times daily. Wash hands with soap. Children under 2 years of age: consult a doctor. to apply to face, spray into palm of hand and gently apply.

Inactive ingredients

Aloe Barbadensis Leaf Extract

Carbomer

Diazolidinyl Urea

Disodium Cocoamphodipropionate

Disodium EDTA

Glycerin

Methylparaben

Propylene Glycol

Propylparaben

SD Alcohol 40

Simethicone

Tocopheryl Acetate

Triethanolamine

BURN RELIEF CONTINUOUS

lidocaine spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:21130-144
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.5 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALCOHOL (UNII: 3K9958V90M)	
DISODIUM COCOAMPHODIPROPIONATE (UNII: 6K8PRP397M)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:21130-144-01	128 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/09/2020	

Labeler - Safeway (009137209)

Establishment

Name	Address	ID/FEI	Business Operations
Inspec Solutions LLC.		081030372	manufacture(21130-144)